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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,243	10/27/2003	Stephen Hamilton	GFI/109 CIP	4492

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EXAMINER	
GUZO, DAVID	
ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
05/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,243	HAMILTON, STEPHEN	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-38 and 40-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *54-55* is/are allowed.

6)☒ Claim(s) *17-38 and 40-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-38 and 40-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record in the previous Office Action (mailed 8/9/2006) and for reasons outlined below.

Applicant traverses this rejection by asserting that the claimed method for modifying glycosylation structures on proteins expressed in eukaryotic cells can be practiced using any endomannosidase provided that the endomannosidase has the activity as defined in the specification which is also set forth under the IUBMB No. EC 3.2.1.130. Applicant asserts that one of skill in the art would reasonable know how to practice the method of the claimed invention because the endomannosidase activity is well-characterized and known in the art. Applicant also asserts that the claimed invention is not directed to specific endomannosidases or endomannosidase genes but instead to a method for altering protein glycosylation structures in eukaryotic host cells by introducing into said cells a nucleic acid encoding endomannosidase activity. Applicant argues that because one of skill in the art can use any endomannosidase

(disclosed in the instant specification or in the prior art) in the claimed method, there would be no undue experimentation required to carry out the full scope of the claimed invention.

Applicant's arguments filed 2/2/07 have been fully considered but they are not persuasive. Applicant's primary argument appears to revolve around the instant claims being method claims for altering protein glycosylation in cells wherein said claims do not read on specific endomannosidases or genes encoding endomannosidases. This argument is not persuasive because the claims read on altering protein glycosylation using **any nucleic acid sequence encoding any endomannosidase protein**. The claim **as a whole** must be analyzed when ascertaining whether the claim satisfies the written description requirement of 35 USC 112, 1st paragraph and the instant claims require a description of the nucleic acid sequences of any nucleic acid sequence encoding any endomannosidase protein and the expression of said nucleic acids in any eukaryotic cell so as to generate enzymatically active endomannosidase proteins which alter protein glycosylation patterns in said cell. The instant claims therefore read on a **genus** of methods wherein each method reads on expressing, in the host cell, a different nucleic acid sequence encoding a different endomannosidase protein selected from a **genus** of nucleic acid sequences encoding any endomannosidase proteins.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed

correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. Clearly, the specification and prior art only teach sequences encoding three different endomannosidases from three different species. In the instant case, applicant has not presented a structure function relationship correlating the structure of the endomannosidases and their function. Additionally, it is noted that the claims encompass a method for modifying glycosylation structures on any protein expressed in any eukaryotic cell by expressing a recombinant nucleic acid encoding any protein having an "endomannosidase activity". This reads on expression of any variant, mutant, allele, derivative or homolog of an endomannosidase protein from any species or source or a fusion protein comprising a portion comprising a protein (or peptide) having endomannosidase activity, etc. With regard to applicant's argument that the skilled artisan would be able to practice the instant invention using any endomannosidase coding sequence because endomannosidases activity is well characterized, it is noted that the description requirement cannot generally be satisfied by describing molecules by function only. As noted in MPEP 2163:

A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. Cf. *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103).

With regard to applicant's argument that the skilled artisan could practice the claimed method without undue experimentation, it is noted that this argument seems to pertain to an enablement rejection since undue experimentation is not a consideration with regard to whether the specification and prior art provide teachings sufficient to describe the claimed subject matter. As further noted in MPEP 2163:

The written description requirement is separate and distinct from the enablement requirement. *In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) (While acknowledging that some of its cases concerning the written description requirement and the enablement requirement are confusing, the Federal Circuit reaffirmed that under 35 U.S.C. 112, first paragraph, the written description requirement is separate and distinct from the enablement requirement and gave an example thereof.). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975) ("[A] specification which describes' does not necessarily also enable' one skilled in the art to make or use the claimed invention."). Best mode is a separate and distinct requirement from the enablement requirement. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

Applicant's argument that the invention can be practiced using any endomannosidase misses the point of the written description rejection in that the instant specification and prior art do not describe a representative number of sequences encoding endomannosidase proteins, do not identify the relevant identifying characteristics of the endomannosidases and do not provide a structure-function relationship between the structure of the endomannosidase protein and the function of said protein as an endomannosidase. While the instant claims encompass use of any

endomannosidase gene, the instant specification clearly does not provide a written description of the genus of sequences encoding said endomannosidase proteins.

Claims 54-55 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
April 18, 2007

DAVID GUZO
PRIMARY EXAMINER